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EXAMINER	
FORD, JOHN M	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/831305	Applicant(s) Yayun Dai
	Examiner T. M Ford	Group Art Unit 1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ Responsive to communication(s) filed on 3.27.03.

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 58--82 and 84--125 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 58--82 and 84--125 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 58--79 and 86--125 are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)–(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)–(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO–1449, Paper No(s). _____

☐ Interview Summary, PTO–413

☐ Notice of Reference(s) Cited, PTO–892

☐ Notice of Informal Patent Application, PTO–152

☐ Notice of Draftsperson's Patent Drawing Review, PTO–948

☐ Other _____

Office Action Summary

Applicants response of March 27, 2003, is noted.

The claims in the application are claims 58--82 and 84--125.

This is a 371 application, 37 CFR 1.475 makes it clear that applicants are entitled to have one specific use of their compounds examined therewith.

Claim 58 is not specific, nor one utility. See claim 59, and 61 and 62.

Claims 58--63 are not limited to one specific real world disease. The method for inhibiting growth factor receptor tyrosine kinase activity does not meet the requirements of 35 U.S.C. 12, 1st paragraph, as it is not a real world disease.

The recent utility guidelines set by PTO require applicants to meet the requirements as stated in Brenner v. Manson in , 148 USPQ 689, which requires that utility be developed to a point where "specific benefits exist in currently available from". Similar is the "immediate benefit to the public" standard that Nelson v. Bowler, 206 USPQ 419 is "whether the invention has been brought to such perfection as to be capable of practice employment". This language is echoed in Bindra vs. Kelly, 206 USPQ 570.

Applicants need to elect one Real World of Commerce disease.

MPEP 806.05(h) provides for restriction. A broad disclosure of utility, as in the cited claims, cannot be deemed in compliance with 35 U.S.C. 101, and 35 U.S.C. 112, first paragraph.

The PTO has amended the guidelines to clarify "specific utility".

The court focused on the fact that the applicant failed to identify a "specific utility" in Brenner v. Manson.

This requirement of one specific utility is consistent with Unity of Invention Practice in International Applications and National Phase Applications under 35 U.S.C. 371, and PCT Rule 13.2 for PCT applications.

Therefore, applicants should limit the method claims to a "specific utility".

Failure to elect within the SSP time limit will result in the method and composition claims being held withdrawn.

Heteroaryl, in claims 58, 63, 64, and 65, does not meet the requirements of 35 U.S.C. 112, 1st or 2nd paragraph.

One on reading heteroaryl has no idea whether the ring is mono cyclic or more. What the hetero atoms are or where they are located in what size ring.

The support in the specification is inadequate for the breadth claimed.

Claim 1 is rejected under 35 U.S.C. 112, 1st and 2nd paragraphs.

What is intended by aryl and heteroaryl?

Heterocyclic is a huge area of Chemistry, that completely overshadows the formula I,

The heteroaryl term is not set forth in clear, specific language. The reader must produce the heterocyclic ring, in question.

Judge Smith noted many different definitions for aryl in the footnotes of In re Sus, 134 USPQ 301. If, therefore, becomes necessary for applicants to indicate in the claims what they intend by aryl. Heteroaryl, likewise, means many different things to different people. Some definitions of heterocyclic include B, P and As as hetero atoms. The U.S.P.T.O. does not consider

those heterocyclic atoms, and does not classify those patents as hetero rings. What applicants intend need be found in the claim.

The specification serves various purposes, it sets forth the prior art, that which applicants found unsuccessful, a defensive publication, that which applicants decided not to claim, or compounds that step the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

The heteroaryl term is not acceptable, as it reads on heterocyclic rings that require specific conception by the reader. Specific, producible, heterocyclic rings are not set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

Exactly what ring is being claimed must be set forth in the claim.

Conception of what the intended heteroaryl ring, may be, should not be left to the reader.

Where is, what is intended by applicant, supported in the specification with sufficient representative exemplification? Note United Carbon Co. vs. Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately defined to be patentable", above at 386.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basic groups for rejecting claims under 35 U.S.C. 112; first is that language used is not precise enough to provide a clear-cut indication of scope of subject matter embraced by claim; this ground finds its basis in second paragraph of section 112; second is that language is so broad that it causes the claim to have a potential scope of protection beyond that which is justified by

specification disclosure; this ground terms from first paragraph of section 12, merits of language in clam must be tested in light of these two requirements.

The heteroaryl variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by rhe claim. The heterocyclic concept is so broad that cause the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here in the specification. Conception should not be the role the reader. Applicants should, in return for a 17/20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second paragraph rejection. If you (the public) find that it works, I claim it, is not a proper basis for patentability, In re Kirk, 153 U.S.P.Q. 48 at page 53.

The heterocyclic rings possible is wide open to staggering possibilities.

Applicants place too much conception with the reader. The heterocyclic expression leaves open, which ones: Azines, Diazine, Triazines, Tetrazines. Where are the starting materials in the specification? Adjacent O and S are too strained to be produced.]

Conception of what the intended heterocyclic ring, may be, should not be left to the reader.

One needs to know exactly where, in the ring, the hetero atoms are: 1,2 or 1,3 or 1,4 or 1,2,4 or 1, 3, 4, etc., as each is a different entity, with a separate search.

These are compound claims, one must clearly know what is being claimed.

One, on reading the indication of heterocyclic applied by applicant, has no idea where the hetero atoms are in this unknown ring,.

What are the hetero atoms?

Not all heterocyclic rings have been shown to be producible, as stable, at room temperature. What is the source of the starting materials? Where is the adequate representative exemplification in the specification to support the claim language?

The heterocyclic term presents a problem of lack of clear claiming, and support in the specification for the variables sought.

This rests conception with the reader.

What exactly is intended, and where is that supported in the specification. Not a fair burden in return for applicants receiving a 17/20 year monopoly.

The possible combinations of any number of hetero atoms, in any combination, in multiple size rings is quire large, and not shown by applicants to be available starting materials.

A Markush listing of intended, conceived of, producible, heterocyclic rings is what is needed here, It is not possible to classify and search the molecule unless one knows exactly which heterocyclic ring is being claimed.

The ultimate utility here is a pharmaceutical use. Declarations of unexpected results are often presented in the pharmaceutical arts. Applicants breadth of heteroaryl produces many different heterocyclic rings that could easily affect results.

Applicants need to claim what they have demonstrated as a specific fact.

The heteroaryl expression in claim 1 are not acceptable, as they do not indicate, exactly, clearly, and specifically, what heterocyclic ring is being claimed. These expressions rest specific conception with the reader, and the specification does not include the source of the starting material for the rings which applicant now claims. One must be able to tell from a simple reading of the claim what it does and does not encompass.

Why? Because that compound claim precludes other from making, using, or selling that compound for 17/20 years. Therefore, one must know what compound is being claimed.

The claims measure the invention, United Carbon Co. Vs. Binney & Smith Co., 55 U.S.P.Q. 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in Lockhead Aircraft Corp. Vs. United States, 193 U.S.P.Q. 449, "Claims measure the invention and resolution of invention must be based on what is claimed".

The CCPA in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant". "We have consistently held that no applicant should have limitations of the specification read into a claim the one express statement of the limitation is included in the claim": In re Priest, 199 U.S.P.Q. 11, at 15.

The heteroaryl expression includes adjacent O/S combinations that are unstable. That open ended breadth cannot be allowed. The claim cannot be completely searched, here, until we

know with applicants intend by heteroaryl. See In re Wiggins; 179 USPQ 421 in regard to the rejection of claim 65.

Additionally, the USPTO only recognizes: C,N,O,S,Se or Te as atoms of a heterocyclic ring. Therefore, the is a need for applicants to indicate what they mean by heteroaryl.

Heterocyclic is not just a substituent; it is a whole body of art, larger than the genus claimed here. Researchers often spend their entire life on hetero N heterocyclic compounds, without ever getting to hetero O or hetero S compounds. Many heterocyclic compounds, within the claim, have never been made.

Accordingly, claim 1 is rejected under 35 U.S.C. 112, 1st and 2nd paragraphs. What is being claimed? Where is the adequate representative exemplification in the specification?

Claims 66--69 are rejected, as they are dependent or a rejected claim, but not for reasons within themselves.

Claim 70 is not a proper dependent claim, as it is dependent on a later appearing claim; 35 U.S.C. 112, 4th paragraph. Likewise, claim 73.

Claims 71, 72, and 74 are rejected as being dependent on a rejected claim.

What is the purpose of the proviso statement in claim 63? Is prior art being written around? What prior art? See New Rule 105.

Claim 75 is rejected, as it would contain a rejected portion of claim 58, if written in independent form it would contain a rejected utility portion of claim 58.

Same claim 76. Applicants would have to establish that inhibition of angiogenesis was a real world disease.

Claim 77 is not appropriate as it refers to a later claim, i.e. claim 90, which is not permitted under 35 U.S.C. 112, 4th paragraph.

Claim 78 is rejected under 35 U.S.C. 112, 1st and 2nd paragraphs as the treatment of all primary tumors and metastasis is extremely unlikely.

The Supreme Court declined to expresses a view as to whether patentability can be based on a product shown to inhibit the growth of tumors in laboratory animals. Brenner, Comr. pats V. Manson, (USC 1966) 383 U.S. 519, 148 USPQ 689. The Court did state, however, that Congress did not intend that a patent on a chemical compound, or a process for its production, whose sole "utility" consists of its potential role as an object of use-testing, reasoning the patent system is related to the world of commerce, rather than the realm of philosophy ibid., 148 USPQ at 696.

The utility of a process for producing remissions in patients suffering from chronic myeloid leukemia was established by clinical reports and data, the acceptance of the drug employed by the Food and Drug Administration and by the American Medical Association Council on Pharmacy, the Board noting that remission, not cures, were alleged in the specification. Ex parte Timmis, (POBA 1959) 123 USPQ 581. Evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of claims

directed to a method of treating seven cancers. In re Butting, (CCPA 1969) 418 F2d, 163 USPQ 689.

Claim 79 is rejected under 35 U.S.C. 112, 1st paragraph. The inhibition of FGFR-3 tyrosine kinase is not a real world utility.

Claim 79 does not comply with 35 U.S.C. 112, 4th paragraph, as it is dependent on a later claim 95.

Claim 80 is rejected under 35 U.S.C. 112, 2nd paragraph. What do applicants intend by heteroaryl? Where is the representative support in the specification for heteroaryl? Claim 80 is also rejected under 35 U.S.C. 112, 1st paragraph. What is the reason for the proviso statements? In re Nomiya, 184 USPQ 607, indicates this suggests the presence of close prior art, over which a 35 U.S.C. 103 rejected should be made. See new Rule 105.

Claims 81 and 85 are rejected, as being dependent on a rejected claim.

Claims 82 and 84, 86 and 87 are rejected because of the undefined presence of heteroaryl. See the previous rejections.

Claim 86 is rejected under 35 U.S.C. 112, 1st paragraph, as inhibiting growth factor receptor tyrosine Kinase activity is not a real world utility. It is a Laboratory activity.

Claims 88--95 launch off on far more utilities than can be dealt with in one application. utility method claims per application
The election of one is required; 37 CFR 1.475, PCT Rule 13.2, and MPEP 806.05(h).

Claims 96--125 are rejected as dependent on a rejected claim.

Examination of one method cannot begin until that one method is elected.

Claims 125 and 124 read on more than one tumor which would not comply with 35 U.S.C. 112, 1st paragraph. See the earlier rejection. The treatment of all primary tumors is not acceptable as something that can be established.

John M. Ford:jmr

May 16, 2003

JOHN M. FORD
PRIMARY EXAMINER
Group Art Unit 1624